

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF SOUTH CAROLINA  
FLORENCE DIVISION

Heyward Thomas Jones,  
and Rosalee Jones,

Plaintiffs,

vs.

Ram Medical, Inc., and  
Medline Industries, Inc.,

Defendants.

Civil Action No. 4:10-cv-2974-TLW

**ORDER**

This matter is now before the Court for consideration of two motions to dismiss filed by Defendant Ram Medical, Inc., (“Ram Medical”), and two motions to dismiss filed by Defendant Medline Industries, Inc., (“Medline”). (Docs. # 17, 23, 31, and 35). On January 6, 2011, Ram Medical filed a motion to dismiss. (Doc. # 17). On January 14, 2011, Medline filed a motion to dismiss. (Doc. # 23). Plaintiffs Heyward and Rosalee Jones<sup>1</sup> filed an Amended Complaint on January 24, 2011. (Doc. # 26). Ram Medical then filed a motion to dismiss on February 4, 2011, (Doc. # 31), and Medline filed a motion to dismiss on February 7, 2011. (Doc. # 35).<sup>2</sup> Plaintiffs filed a response in opposition to Ram Medical’s motion to dismiss and to Medline’s motion to dismiss on February 22, 2011. (Docs. # 37 and 39). Medline filed a reply on March 8, 2011.

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<sup>1</sup> This Court acknowledges that Plaintiff Rosalee Jones seeks recovery only under a claim for “loss of consortium.” While this Order may often refer to the “Plaintiffs,” the Court notes that it does not intend to imply that Rosalee seeks or is entitled to recovery under any other cause of action.

<sup>2</sup> Ram Medical’s two motions are substantially similar. This Court notes that the first motion includes the argument that the South Carolina Unfair Trade Practices Act (“SCUTPA”) does not permit recovery for personal injury. A corresponding argument is not included in Ram Medical’s second motion to dismiss. Nevertheless this Court has reviewed and considered the arguments put forth by Ram Medical against Plaintiffs’ SCUTPA claim.

(Doc. # 49). The Court has carefully considered the pleadings, motions, and memoranda of the parties, and this matter is now ripe for disposition.

### **Standard of Review**

Federal Rule of Civil Procedure 8(a)(2) provides that a pleading must contain a “short and plain statement of the claim showing that the pleader is entitled to relief.” It has been noted that “[a] motion to dismiss under Rule 12(b)(6) for failure to state a claim upon which relief can be granted is a challenge to the legal sufficiency of a complaint, as governed by Rule 8.” Federal Trade Commission v. Innovative Marketing, Inc., 654 F. Supp.2d 378, 384 (D. Md. 2009). The Supreme Court has recently held that “[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009) (citing Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007)). The Supreme Court noted that “[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged,” and noted that “[d]etermining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” Id. See Harman v. Unisys Corp., 2009 WL 4506463 \*2 (4th Cir. 2009). The Court added that “the tenet that a court must accept as true all of the allegations contained in the complaint is inapplicable to legal conclusions” and that, “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” Id. The Court further noted that “[w]hen there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.” Id. at 1950.

This Court further notes that allegations of fraud pled as the basis of a RICO claim must meet the heightened pleading requirements set forth in Rule 9(b) of the Federal Rules of Civil Procedure. Menasco, Inc. v. Wasserman, 886 F.2d 681, 684 (4th Cir. 1989) (citing Schreiber Distrib. Co. v. Serv-Well Furniture Co., 806 F.2d 1393, 1400-01 (9th Cir. 1986) (“plaintiff must plead ‘circumstances of the fraudulent acts that form the alleged pattern of racketeering activity with sufficient specificity pursuant to Fed. R. Civ. P. 9(b)’”). Rule 9(b) states, “In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.”

Medline has also filed a motion pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure for lack of subject matter jurisdiction. In analyzing a motion under 12(b)(1), “all facts alleged in the complaint are assumed to be true and the plaintiff, in effect, is afforded the same procedural protection as he would receive under rule 12(b)(6) consideration.” Adams v. Bain, 697 F.2d 1213, 1219 (4th Cir. 1982).

### **Discussion**

Plaintiffs brought this suit against Medline and Ram Medical, alleging eleven causes of action in the Amended Complaint. The lawsuit stems from allegations that Defendants sold, manufactured, and or marketed counterfeit and otherwise defective surgical mesh. The surgical mesh in question is used to reinforce soft tissues in the body where a weakness exists, such as in the repair of hernias. Plaintiffs contend the United States Food and Drug Administration (“FDA”) has determined that the surgical mesh manufactured or caused to be manufactured and sold by Defendants is counterfeit. (Am. Compl ¶ 12). Plaintiffs also allege that while certain lots of the mesh were represented to be of the C.R. Bard/Davol brand name and manufactured by C.R. Bard, they were actually counterfeit products manufactured in China. Id.

Plaintiff Heyward Jones underwent a surgical procedure which allegedly involved the implantation of the counterfeit surgical mesh. Heyward alleges that after his surgery he developed a severe abdominal staph infection which required multiple corrective surgical procedures. (Am. Compl. ¶ 20). Heyward now seeks recovery from Defendants on claims of negligence, products liability, breach of warranty, fraud, violation of the South Carolina Unfair Trade Practices Act (“SCUTPA”), and violation of the Federal Racketeer Influenced and Corrupt Organizations Act, (“RICO”). Plaintiff Heyward’s spouse seeks compensation for loss of consortium.

### **Breach of Warranty Claims**

Defendant Ram Medical first contends that all of Plaintiffs’ breach of warranty claims fail because the warranty provisions of South Carolina’s Uniform Commercial Code (“UCC”) do not govern the instant transaction. Ram Medical argues Article II of the UCC applies only to transactions in goods, and the instant transaction is a contract for services. Ram Medical notes that South Carolina caselaw makes clear that health care providers offer services, not products. See In re Breast Implant Product Liability Litig., 503 S.E.2d 445, 452 (S.C. 1998). Accordingly, Ram Medical contends that a transaction where a physician implants surgical products into a patient is not governed by the UCC because the provision of health care constitutes the sale of services.

This Court finds Ram Medical’s position unpersuasive. Ram Medical has not established that it is a health care provider. The pleadings assert that Ram Medical is a dealer in goods, namely medical products. (Am. Compl. ¶ 3). Moreover, Plaintiffs contend the predominant factor test used to analyze transactions that contain both the sale of goods and services favors a finding that the UCC governs the instant transaction. If the predominant factor is the sale of

goods with labor incidentally involved, the UCC applies. See Ranger Constr. Co. v. Dixie Floor Co., 433 F.Supp. 442, 445 (D.S.C. 1977). Plaintiffs contend the South Carolina Court of Appeals has noted that in most cases in which the contract includes both services and the sale of goods, courts have applied the UCC. Plantation Shutter Co., Inc. v. Ezell, 492 S.E.2d 404 (S.C. Ct. App. 1997). This Court is persuaded by the arguments put forth by the Plaintiffs. Accordingly, this Court finds that at this stage of the litigation, the Plaintiffs have sufficiently pled that the UCC applies to the instant transaction.

### **Express Warranty**

Ram Medical argues it did not create an express warranty under South Carolina law. In order to establish a cause of action for breach of express warranty in South Carolina, a plaintiff must prove (1) the existence of an express warranty, (2) breach of the express warranty, and (3) damages proximately caused by the breach. Thomas v. Louisiana-Pacific Corp., 246 F.R.D. 505, 511 (D.S.C. 2007). Ram Medical argues that while the South Carolina Court of Appeals has determined that a manufacturer's assertions in an advertisement may create an express warranty, no South Carolina court has held that a distributor creates an express warranty through another's marketing, advertising, packaging, promotional material, or label by selling another's goods. See Triple E, Inc., v. Hendrix & Dail, Inc., 543 S.E.2d 245 (S.C. Ct. App. 2001). Ram Medical argues the formation of an express warranty requires reliance by the plaintiff on an affirmation of fact or promise by the party against whom the purported warranty is sought to be enforced. Id. at 247. Ram Medical contends it did not package or label the product in question, but merely acquired and re-sold the product. Therefore, Ram Medical argues it should not be held liable for any affirmations made by the manufacturer of the products in question.

The Plaintiffs contend the existence of an express warranty running from Ram Medical to Plaintiff Jones has been properly pled. The Plaintiffs note that S.C. Code. § 36-2-102(1) provides “Any affirmation of fact or promise, including those on containers or labels, made by the seller to the buyer, whether directly or indirectly, which relates to the goods and becomes a basis of the bargain creates an express warranty that the goods conform to the affirmation or promise.” S.C. Code § 36-2-318 explains further, “A seller’s warranty whether express or implied extends to any natural person who may be expected to use, consume or be affected by the goods and whose person or property is damaged by breach of the warranty.”

Plaintiffs note they have pled that Defendants expressly warranted to Plaintiff’s treating physicians that the mesh had certain qualities and characteristics which were in fact untrue. (Am. Comp. ¶ 58). Moreover, Plaintiffs note that the FDA has traced the alleged malfeasance of manufacturing and labeling the mesh as a product created by C.R. Bard to the named Defendants. The Court finds persuasive the position set forth by the Plaintiffs. Accordingly, the Court finds the Plaintiffs have sufficiently pled a claim for breach of an express warranty against Ram Medical.

Ram Medical also contends Plaintiffs have not pled facts sufficient to sustain an action for breach of an express warranty because Plaintiffs have not pled the language alleged to have created the express warranty. This Court finds the language present in the Amended Complaint as well as the Amended Complaint’s reference to an alleged photocopy of the actual surgical sticker included by Defendants in the packaging which stated the product was “Bard Mesh” is sufficient to state a claim for breach of an express warranty.

### **Implied Warranty of fitness for a Particular Purpose**

Medline contends that Plaintiffs' cause of action for breach of implied warranty of fitness for a particular purpose fails because the purpose alleged by the Plaintiff is the usual purpose for the mesh and not some particular purpose different from its usual use. Medline argues further that there are no specific facts from which one could reasonably conclude that Plaintiff knew what brand of mesh his surgeon would use or to conclude that Plaintiff relied on any representations Medline may have made.

Ram Medical argues further that this cause of action should fail because the vendor had no reason to know when the contract was formed that the purchaser was relying on the vendor's skill or judgment in furnishing the goods. Ram Medical also contends it had no reason to know of the "particular purpose" for which the mesh would be used.

S.C. Code § 36-2-315 reads, "Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is . . . an implied warranty that the goods shall be fit for such purpose." Plaintiffs assert that Defendants had reason to know of the particular purpose for which the mesh was to be used and that Defendants knew the buyer was relying on Defendants' skill or judgment. (Am. Comp. ¶ 69). Plaintiffs assert this particular purpose is the use of the surgical mesh for implantation into the human body to reinforce a port used in conjunction with an adjustable gastric band. *Id.* at ¶ 70.

Plaintiffs also assert that Defendants argument concerning whether Plaintiff's use of the product differed from its ordinary use is foreclosed by South Carolina caselaw. In Soaper v. Hope Indus., Inc., 424 S.E.2d 493, 495 (S.C. 1992) the South Carolina Supreme Court stated, "Where the particular purpose for which a product is purchased is also the ordinary or intended

purpose of the product, the warranties of merchantability and of fitness for a particular purpose merge and are cumulative, such that a plaintiff may proceed upon either theory.” The court further noted, “Where a product is not fit for any purpose, it is not fit for its particular purpose.”

The Court finds that, at this stage of the litigation, Plaintiffs have sufficiently pled its claim for breach of implied warranty of fitness for a particular purpose. Moreover, the Court finds the controlling caselaw on this issue supports a finding that Plaintiff’s may proceed on this cause of action.

### **South Carolina Unfair Trade Practices Act**

Both Medline and Ram Medical argue Plaintiffs SCUTPA claim fails to state a claim upon which relief may be granted because Plaintiffs seek recovery for personal injury, and the SCUTPA does not permit recovery for personal injury damages. S.C. Code § 39-5-20(a) declares unlawful “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce . . . .” Defendants state the only case to have entertained this specific question held that SCUTPA is not a proper remedy for personal injury. Little v. Brown Williamson Tobacco Corp., 1999 WL 33291385 (D.S.C. Mar. 3, 1999).

Plaintiffs argue that the statute provides for recovery for the losses allegedly suffered in this action. S.C. Code Ann. § 39-5-140(a) explains, “Any person who suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of an unfair or deceptive method, act or practice declared unlawful by § 39-5-20 may bring an action individually, but not in a representative capacity, to recover actual damages.” In Little, which is cited by the Defendants, the court noted that the “plaintiffs may have an action to recover their medical costs, lost earnings, and any other alleged out-of-pocket expenses” under the SCUTPA. Little, 1999 WL 33291385 at \* 11 (citing S.C. Code § 39-5-140(a)). Accordingly,



the Court finds the Plaintiffs have sufficiently pled an injury for which recovery may be sought under the SCUTPA.

Ram Medical next argues SCUTPA does not apply to “[a]ctions or transactions permitted under laws administered by any regulatory body or officer acting under statutory authority of this State or the United States or actions or transactions permitted by any other South Carolina state law.” S.C. Code § 39-5-40(a). Ram Medical contends the FDA regulates the product, packaging, and labeling from which Plaintiff’s allegations arise. Therefore, according to the Defendant, because the FDA regulates packaging and labeling, Plaintiffs cannot recover under SCUTPA as a matter of law.

Plaintiffs have alleged that Defendants marketed and distributed a counterfeit product. Moreover, Plaintiffs contend Ram Medical is currently under investigation by the FDA for alleged violations of FDA regulations. Therefore, Plaintiffs’ have alleged that Defendants have acted in a manner which is clearly not permitted under FDA regulations. Accordingly, this Court finds the Plaintiff’s pleadings sufficient to state a claim for relief under SCUPTA.

Finally Ram Medical argues Plaintiff Rosalee Jones cannot recover under SCUPTA because she has not alleged an ascertainable loss and seeks to recover in a representative capacity. Plaintiffs note that Rosalee Jones has only joined in the eleventh cause of action for loss of consortium and has not joined in the claim for violation of the SCUPTA. Accordingly, this Court finds that since Rosalee Jones is not seeking recovery under the SCUPTA, there is no issue to be resolved.

### **Federal Racketeer Influenced and Corrupt Organizations Act (“RICO”)**

To establish a claim under RICO, a plaintiff must show: (1) a violation of 18 U.S.C. § 1962, (2) an injury to business or property, and (3) that the injury was caused by the violation of

§ 1962. See Palmetto State Medical Ctr. V. Operation Lifeline, 117 F.3d 142, 148 (4th Cir. 1997). Under § 1962(c), a plaintiff must allege:

(1) a defendant person (2) employed or associated with (3) an enterprise, engaged in, or the activities of which affect, interstate or foreign commerce, (4) conducts or participates in the conduct of the affairs of the enterprise (5) through a pattern of racketeering activity.

Sadighi v. Daghighfekr, 36 F. Supp.2d 279, 295-96 (D.S.C. 1999).

It is noted that “RICO treatment is reserved for conduct ‘whose scope and persistence pose a special threat to social well-being.’” GE Inv. Private Placement Partners II v. Parker, 247 F.3d 543, 551 (4th Cir. 2001) (quoting Menasco, Inc. v. Wasserman, 886 F.2d 681, 684 (4th Cir. 1989).

Medline notes that in RICO cases, “Any allegation of personal injury and pecuniary losses occurring therefrom are not sufficient to meet the statutory requirement of injury to ‘business or property.’” Blast v. Cohen, Dunn & Sinclair, P.C., 59 F.3d 492, 495 (4th Cir. 1995) citing Doe v. Roe, 958 F.2d 763, 767-70 (7th Cir. 1992). Both Defendants argue Plaintiffs’ RICO claim should be dismissed. First, Defendants contend RICO was enacted to deal with commercial losses resulting from racketeering activity and has been uniformly held inapplicable to actions for personal injury, including economic loss from personal injury. 18 U.S.C. § 1964(c) states that civil remedies under RICO are limited to “[a]ny person injured in his business or property by reason of a violation of section 1962 of this chapter . . . .” In support, Defendants cite Drake v. B.F. Goodrich Co., 782 F.2d 638, 644 (6th Cir. 1986), Grogan v. Platt, 835 F.2d 844 (11th Cir. 1988), and Brandenburg v. Seidel, 859 F.2d 1179, 1187 (4th Cir. 1988). Medline argues further that because Plaintiffs have failed to allege recoverable damages, this Court does not have subject matter jurisdiction over this claim and therefore it should be dismissed pursuant

to Rule 12(b)(1). Defendants argue all of the damages Plaintiffs allege are pecuniary losses occurring from the alleged personal injury and therefore are not damages recoverable under a RICO cause of action.

Plaintiffs respond by noting that while damages for personal injuries are sought under other causes of action, Plaintiffs seek additional damages under RICO that do not stem from personal injury. Plaintiffs note recovery is sought for economic loss, the cost of the counterfeit surgical mesh, the costs of implanting and explanting the counterfeit mesh, and loss of income. (Am. Compl. ¶ 134). In support, the Plaintiff cites In re Cordis Corp. Pacemaker Product Liability Litig., 1992 WL 754061 (S.D. Ohio 1992). Plaintiffs contend this case is perhaps one of the only cases which specifically addresses a scenario factually similar to the case at hand. Cordis involved litigation over the dissemination of defective pacemakers.

In Cordis, the plaintiffs brought a class action suit against Cordis, a manufacturer of pacemakers, for injuries suffered from the implantation of an allegedly defective pacemaker. The defendants moved to dismiss the RICO claim for, among other reasons, failure to allege injuries for which RICO provides a remedy. The court stated that “RICO does not provide a remedy for physical injuries or emotional harm.” Id. at \*3. However, the court noted that the plaintiffs also sought recovery of “property damages such as the cost of the pacemakers and the cost of implanting and explanting them.” Id. The court in Cordis stated:

[J]ust as a consumer who purchases a product, sold in violation of antitrust statutes, can suffer an injury to his or her property (the inflated price of the product), a consumer who purchases a defective product, sold in violation of RICO, can also suffer an injury to his or her property (the diminished value of the product and costs associated with implanting and explanting the product).

Id.

This Court finds certain caselaw concludes that RICO does not provide a remedy for physical injuries or emotional harm. Moreover, certain caselaw holds it does not provide a remedy for pecuniary injury in the form of lost income or lost wages. However, this Court finds the Plaintiff in the instant litigation has sufficiently pled damages related to the cost of the surgical mesh as well as the cost of implanting and explanting the mesh to survive a motion to dismiss.

Defendants next contend that Plaintiffs have failed to plead a “pattern of racketeering,” which requires a series of identifiable predicate acts that fall within the scope of 18 U.S.C. § 1961. Defendants provide four reasons for why Plaintiffs have failed to establish a pattern of racketeering activity as a matter of law: “(1) Plaintiffs fail to establish the requisite predicate acts of mail and wire fraud, (2) Plaintiffs fail to establish related and continuing predicate acts, (3) Plaintiffs fail to establish predicate acts occurring over a substantial period of time, and (4) Plaintiffs allege only a limited, narrow scheme which is insufficient to establish a pattern of racketeering.” Def. Summ J. at p. 8, (Doc. 31-1).

As to Defendants first challenge, the Fourth Circuit has noted “A pattern of racketeering requires at least two predicate acts.” Al-Abood v. El-Shamari, 217 F.3d 225, 238 (4th Cir. 2000). See also 18 U.S.C. § 1961(5). These predicate acts include “trafficking in goods or services bearing counterfeit marks,” “mail fraud,” and “wire fraud.” 18 U.S.C. § 1961(1) (citing 18 U.S.C. §§ 2320, 1341, and 1343). Defendants argue Plaintiff has alleged nothing more than garden-variety personal injury products liability claims predicated upon broad, conclusory allegations insufficient to constitute a RICO cause of action.

This Court finds that Plaintiffs have satisfied the pleading requirements set forth under Rules 8(a) and 9(b) of the Federal Rules of Civil Procedure as to the requirement that two or

more predicate acts of racketeering be pled. First, the Court finds Plaintiffs have sufficiently pled two or more instances of trafficking in counterfeit goods. Plaintiffs have alleged that Defendants intentionally manufactured, distributed, and sold surgical mesh that they knew was counterfeit. (Am. Compl. ¶ 118). Plaintiffs note that they have alleged that Defendants' trafficking resulted in the distribution of at least fifteen lots of counterfeit mesh to numerous states. *Id.* at ¶ 119. Plaintiffs note further that this allegation is supported by an FDA notice of recall in which the FDA identifies the specific lot numbers of the counterfeit mesh that Defendants placed into the stream of commerce. Plaintiffs have also pled that the FDA notice of recall states that RAM Medical sold the counterfeit products. Finally, Plaintiffs have pled that Defendants' predicate acts of trafficking in counterfeit goods have resulted in the implantation of counterfeit surgical mesh in a number of individuals. (Am. Compl. ¶ 120). Accordingly, this Court finds that Plaintiffs have sufficiently pled allegations of two or more predicate acts of racketeering activity in relation to the trafficking goods bearing counterfeit marks.

As to the claim of mail fraud, 18 U.S.C. § 1341 states, "Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of fraudulent pretenses," uses the mails "for the purpose of executing such scheme or artifice or attempting to do so" is guilty of mail fraud. "The gravamen of the offense is the scheme to defraud, and any 'mailing that is incident to an essential part of the scheme satisfies the mailing element,' even if the mailing itself 'contain[s] no false information.'" Bridge v. Phoenix Bond & Indemnity Co., 553 U.S. 639, 647 (2008) (citing Schmuck v. United States, 489 U.S. 705, 712-15 (1989)).

As to the claim of wire fraud, 18 U.S.C. § 1343 states, "Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by

means of false or fraudulent pretenses . . . transmits or causes to be transmitted by means of wire, radio, or television communication in interstate or foreign commerce, any writings, signs, signal, pictures, or sounds for the purpose of executing such scheme or artifice” shall be guilty of wire fraud. For a wire fraud claim, the plaintiff must allege “1) a scheme to defraud and 2) the use of a wire communication in furtherance of that scheme.” United States v. Bollin, 264 F.3d 391, 407 (4th Cir. 2001).

With regard to both mail fraud and wire fraud claims, Rule 9(b) of the Federal Rules of Civil Procedure requires that allegations of fraud be pleaded with particularity. Accordingly, a RICO claim premised upon either wire fraud or mail fraud predicate acts must be pleaded with particularity. See Mylan Lab. Inc. v. Matkari, 7 F.3d 1130, 1137 (4th Cir. 1993).

This Court finds that Plaintiffs have adequately pled facts with sufficient particularity to satisfy Rule 9(b) that two or more predicate acts of racketeering activity have occurred through Defendants’ alleged mail fraud and wire fraud. The Court finds that ¶¶ 123 and 124 of Plaintiffs’ Amended Complaint allege a scheme to defraud through the mail with sufficient particularity as to the time, place, and content of the alleged fraud to satisfy the requirements of Rule 9(b). In addition, the Court finds that ¶¶ 127 and 128 of Plaintiffs’ Amended Complaint similarly satisfy the same Rule 9(b) requirements. Therefore, this Court finds that the plaintiffs have sufficiently established the requisite predicate acts of mail and wire fraud at this stage of the litigation.

Defendants next challenge Plaintiffs’ ability to allege a pattern of related, continuing predicate acts sufficient to state a RICO claim. “To establish a pattern of racketeering activity, the plaintiff must show that the predicate acts are related and that they ‘amount to or pose a threat of continued criminal activity.’” GE Inv. Private Placement Partners II, v. Parker, 247 F.3d 543, 549 (4th Cir. 2001) (citing H.J. Inc. v. Nw. Bell Tel. Co., 492 U.S. 229, 239 (1989)). “It is

this factor of *continuity plus relationship* which combines to produce a pattern.” H.J. Inc. v. Nw. Bell Tel. Co., 492 U.S. at 239. To be deemed related, predicate acts “must have ‘the same or similar purposes, results, participants, victims, or methods of commission, or otherwise [be] interrelated by distinguishing characteristics and [not be] isolated events.’” ePlus Tech. Inc. v. Aboud, 313 F.3d 166, 182 (4th Cir. 2002) (citing H.J. Inc. at 240).

It is further noted, “The continuity aspect . . . refers ‘either to a closed period of repeated conduct, or to past conduct that by its nature projects into the future with a threat of repetition.’” ePlus Tech, 313 F.3d at 182 (citing H.J. Inc. at 241). Moreover, “‘Predicate acts extending over a few weeks or months and threatening no future criminal conduct do not satisfy this requirement: Congress was concerned in RICO with long-term criminal conduct.’” Id. (citing H.J. Inc. at 242). “Thus, it is clear that predicate acts of racketeering activity must be part of a prolonged criminal endeavor.” Id.

Defendants argue Plaintiffs reference only a single, narrow alleged scheme and do not sufficiently allege that the acts are related. Plaintiffs contend the element of relatedness has been sufficiently alleged. Plaintiffs point to the FDA Notice of Recall and argue that Defendants have distributed and sold fifteen lots of counterfeit surgical mesh. Plaintiffs allege there are potentially one hundred fifty individual victims that have been implanted with counterfeit surgical mesh. Am. Compl. ¶ 120). Plaintiffs argue further that the purpose of the sale was to defraud individual patients into paying full price for an inferior counterfeit good, which is common to all potential victims. Id. at ¶ 129 Plaintiffs allege the results were common in that each victim paid for and was implanted with a counterfeit product. Plaintiffs next contend the participants were common because the FDA has implicated seven distributors who were responsible for the dissemination of the counterfeit mesh. Plaintiffs allege the victims who are individual patients who trusted the

source of the products provided to their healthcare providers were also common. Finally, Plaintiffs argue the method of commission was common in that Defendants established distribution networks to disseminate counterfeit products. This Court finds persuasive the arguments set forth by the Plaintiffs. Accordingly, this Court finds Plaintiffs have sufficiently pled the element of “relatedness.”

Defendants argue Plaintiffs have failed to sufficiently allege the element of “continuity.” Courts have described continuity as being either “open-ended” or “close-ended.” “Open-ended continuity may be established where, for example, the ‘related predicates themselves involve a distinct threat of long-term racketeering activity,’ or where the predicate acts ‘are part of an ongoing entity’s regular way of doing business . . . or of conducting or participating in an ongoing and legitimate RICO enterprise.’” GE Inv. 247 F.3d at 549) (citing H.J. Inc., 492 U.S. at 242-43). Defendants argue Plaintiffs have failed to assert specific allegations establishing the alleged predicate acts present a threat of future criminal activity. Additionally, Defendants argue that because Plaintiffs assert the alleged predicate acts continued only through March 15, 2010, they have conceded a close-end nature to the alleged predicate acts.

Plaintiffs disagree, and argue that the inquiry extends to whether there is the “threat” of continuation because [o]ften a RICO action will be brought before continuity can be established . . . . In such cases, liability depends on whether the *threat* of continuity is demonstrated.” H.J. Inc., 492 U.S. at 242. Open-ended continuity “may be established by showing that ‘predicate acts or offenses are part of an ongoing entity’s regular way of doing business.’” Anderson v. Found. For Advancement, Educ. And Emp’t of Am. Indians, 155 F.3d 500, 505 (4th Cir. 1998) (citing H.J. Inc., at 242). Plaintiffs assert that the distribution and sale of surgical products through various channels is the primary component of Defendants’ ongoing business operations.



Plaintiffs argue further that Defendants' activities are alleged to have taken place during the scope of Defendants' business operations. Plaintiffs argue Defendants' distribution networks allowed for dissemination of the fifteen lots of counterfeit surgical mesh. Plaintiffs contend the distribution networks remain in operation and therefore the threat that Defendants continue to distribute counterfeit medical products remains. Finally, Plaintiffs assert that Defendants ongoing business relationships with questionable and evasive foreign suppliers further supports its argument that there remains the threat of continued racketeering activity. This Court finds that, based on the allegations set forth in Plaintiffs' Amended Complaint, Plaintiffs have sufficient pled "open-ended" continuity at this stage of the litigation.

This Court finds that Plaintiff has pled allegations sufficient to satisfy the "continuity" requirement of a RICO claim at this stage of the litigation. Plaintiff has done so by satisfying the pleading requirements for "open-ended" continuity. Therefore, this Court finds that it need not address the question of whether Plaintiff can satisfy the requirements of "close-ended" continuity at this time.

Finally, Defendants argue the alleged enterprise and Defendants are not distinct entities as required by 18 U.S.C. § 1962(c). This Court notes that "[t]he enterprise must be distinct from the persons alleged to have violated § 1962(c)." Palmetto State Med. Cent. V. Operation Lifeline, 117 F.3d 142, 148 (4th Cir. 1997) (citing New Beckley Mining Corp. v. Int'l Union, United Mine Workers of Am., 18 F.3d 1161, 1163 (4th Cir. 1994)). An "enterprise" "includes any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4). Moreover, "From the terms of RICO, it is apparent that an association-in-fact enterprise must have at least three structural features: a purpose, relationships among those associated with the enterprise, and

longevity sufficient to permit these associates to pursue the enterprise's purpose." Boyle v. U.S., 129 S.Ct. 2237, 2244 (2009). Defendants contend the Amended Complaint fails to sufficiently identify any entity comprising the enterprise other than the named defendants.

Plaintiffs' allegations state that the enterprise operated separately and distinctly from the named Defendants and that the "enterprise" consists of at least five additional entities which have been implicated in the enterprise's activities by the FDA. (Am. Compl. ¶ 105). Moreover, Plaintiffs allege that the enterprise includes an unnamed overseas supplier. Id. at ¶ 106. Plaintiffs assert further that the enterprise executed a scheme to defraud and conceal from Plaintiffs the fact that the surgical mesh was counterfeit, that the enterprise established standard operating procedures for gathering and disseminating counterfeit medical devices and required the actors to violate FDA safety regulations, and that the enterprise was in operation for a number of years during which the enterprise disseminated at least fifteen lots of counterfeit surgical mesh to the general public. (Am. Compl. ¶¶ 104, 106, 110, and 119). The Court finds that Plaintiffs have adequately pled the existence of an "enterprise" to survive Defendants' motions to dismiss. Accordingly, Defendants' motions to dismiss Plaintiffs RICO cause of action are denied.

### **CONCLUSION**

For the foregoing reasons, defendants' motions to dismiss Plaintiffs' Fourth, Fifth, Sixth, Ninth, and Tenth causes of action are **DENIED**. (Docs. # 17, 23, 31, and 35).

**IT IS SO ORDERED.**

s/Terry L. Wooten  
TERRY L. WOOTEN  
United States District Judge

August 8, 2011  
Florence, South Carolina